

Serial No. 10/047,581

HRT 287

REMARKS

Claims 15-44 remain in this application. Claims 1-14 are cancelled. Claims 33-40 are cancelled, without prejudice, in response to the Examiner's restriction requirement.

The Examiner rejected claims 15-32 and 42-44 under 35 U.S.C. § 103(a) as being unpatentable over Andersen (U.S. Patent No. 5,840,081) in view of Lazarus (U.S. Patent No. 5,104,399) or Sakura (U.S. Patent No. 4,214,587). In addition, while not clearly stated, it appears the Examiner argues in the first paragraph following the above rejection that the combination of Peale (U.S. Patent No. 151,192) and Sakura renders the claims unpatentable. Applicant traverses the rejections.

Taking the Peale-Sakura combination first, Applicant rely on their prior response: the Examiner has failed to establish a prima facie case of obviousness. Claim 15 requires a valve for implantation at a desired location within a mammal that includes a flexible sleeve, at least one cusp configured to permit blood flow through the at least one cusp in a single direction, at least one ring attached to the sleeve, and at least one fastener extending in a direction radially outward with respect to the sleeve. Neither Peale nor Sakura teach or suggest the claimed subject matter of independent claim 15, nor do they teach the elements of the claims that depend from claim 15.

Sakura discloses an anastomosis device for securing, for example, one blood vessel to another blood vessel. Sakura, col 1:6-10. Sakura does not discuss valves or the affixation of valves anywhere in its specification. On the other hand, as described above, Peale discloses *valves for syringes, pumps and other instruments* that are "intended to imitate as nearly as may be, the valves of the arterial, and other portions, of the human organization ..." (Peale, col 1, lines 10-13). Peale does not teach a valve designed to be implanted in a mammal. Applicants representative has studied Peale and can find no discussion of how Peale is affixed within the syringes, pumps or other instruments. The Examiner concludes that Peale is affixed with a friction fit. Peale, however, does not identify affixation as an issue. As a result, Applicant sees no motivation or suggestion to combine Sakura and Peale. Further, even if Sakura and Peale

Serial No. 10/047,581

HRT 287

were combined, there is no teaching that such a combination would succeed. While the valve of Peale is described as flexible, there is no teaching that Peale the tube of Peale would be flexible enough to be inverted, as the vessel end 31 of vessel 30 is inverted over the anastomotic device 10 of Sakura. Nothing in Sakura or Peale teaches a motivate to combine the two references, nor do they teach how the references could be combined in a way that would work.

Further, in addition to being allowable as dependent from either independent claim 15, dependent claims 16-32 and 42-44 are patentable in their own right. Taking a few examples, neither Sakura nor Peale describe or suggest: a valve that includes a sleeve and a ring attached to the sleeve at the proximal end, as claimed in claim 21; the valve of claim 15, where the ring is attached to the outer surface of the sleeve, as claimed in claim 22; the valve of claim 15, where the fastener includes a series of legs arranged circumferentially about the ring, as claimed in claim 26; the valve of claim 15, where the ring has a longitudinal axis and the fastener includes at least one mounting pin attached to the mounting ring, the mounting pin having two ends offset from one another in the longitudinal direction, as claimed in claim 27; the valve of claim 15, where the two ends of the at least one mounting pin extend radially outward from the mounting ring, as claimed in claim 28; or, the valve of claim 15, wherein the mounting ring is balloon expandable, as claimed in claim 29.

As a result, Applicant submits that the rejection is overcome and requests the Examiner to withdraw the obviousness rejection with respect to claims 15-32 and 42-44.

As to the rejection based on Andersen in combination with Lazarus or Sakura, Applicant traverses this rejection. Andersen was filed in Denmark on May 18, 1990, and did not publish until November 28, 1991 as a PCT application. This application claims priority back to July 16, 1991. As a result, Andersen is not prior art to this application as this application benefits from a priority date that is prior to the publication of the Andersen patent application. Thus, the obviousness rejections based on the combination of Andersen with Sakura or Lazarus are no longer supported. Further, neither Sakura nor Lazarus teach or suggest the elements claimed in claims 15-32 and 42-44. Applicant, therefore, requests the Examiner to withdraw the rejection.

Serial No. 10/047,581

HRT 287

Applicants grant the PTO permission to charge the deposit account no. 10-0750/BST/HRT0287 for any fees or charges related to this application. Applicant respectfully requests the Examiner to contact the below-signed if a discussion regarding the merits would advance prosecution of this case.

Respectfully submitted,

By: _____/BS Tomko/
Brian S. Tomko
Reg. No. 41,349

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1239
Dated: April 28, 2005